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### **Kansas Immunization Program Wasted VFC Vaccine Policy**

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The Vaccines for Children (VFC) Program requires the Kansas Immunization Program (KIP) ensure that VFC provider vaccine management practices are consistent with sound immunization, fiscal, business and medical practices, and do not result in unnecessary costs to the program due to excessive wastage or unaccounted for VFC vaccines. The Centers for Disease Control and Prevention (CDC) have established minimum guidelines detailing the steps of proper vaccine storage and handling. This toolkit is found at:

<http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>

Kansas VFC providers are diligent in their practices to ensure sound vaccine management practices. The Kansas Immunization Program appreciates these efforts. These vaccine management policies are designed to help assure continuation of the VFC program for Kansas children by:

- a. Assisting each provider clinic in quality improvements in VFC vaccine management practices
- b. Reducing wasted vaccines
- c. Ensuring vaccines are stored appropriately so they are stable
- d. Decreasing and/or eliminating unaccounted for vaccines

Clinic policies and procedures shall be updated annually with signature and date. Program staff will review each clinic's policies and procedures at the VFC compliance site visit and/or unannounced visits. VFC providers must have policies and procedures to address management of VFC vaccines in each of the following areas; Vaccine Storage and Handling, Vaccine Ordering, Vaccine Borrowing, Wasted Vaccine and Emergency Management.

#### **Wasted VFC Vaccine Policy**

The Kansas Immunization Program (KIP) is charged with reducing Vaccines for Children (VFC) vaccine losses due to wasted vaccines. Thousands of doses are wasted annually with values exceeding hundreds of thousands of dollars. This is a needless waste of federal and state tax dollars and adversely impacts the numbers of eligible children who could receive immunizations.

The Centers for Disease Control & Prevention (CDC) strengthened the VFC Program non-compliance processes beginning in 2009. In 2012, the Office of Inspector General (OIG) mandated the CDC become increasingly focused on stopping needless vaccine waste, improve storage and handling of vaccines, and increase program and provider accountability for vaccine resources. All state immunization programs implemented wasted vaccine policies aimed at identifying and preventing waste, poor vaccine management processes, and/or fraud or abuse in the VFC program. Vaccine management processes, including documentation, proper vaccine storage and handling, reporting vaccine usage, determining VFC eligibility, temperature monitoring, and preventing avoidable waste, are critical to this compliance program.

KIP's goal is to educate and assist providers in identifying mechanisms to prevent wasted vaccines and improve overall vaccine management processes. This policy is one component of these processes.

## Provider Processes:

1. Complete or submit these documents by the 7<sup>th</sup> of the month following the month of service:
  - a. Monthly vaccine inventory reconciliation in KSWebIZ; (Reconciliations must be from the 1<sup>st</sup> of the month to the last day of the month)
  - b. Temperature logs or data logger downloads;
  - c. Wasted vaccine completed within KSWebIZ within 72 hours of vaccine wastage;
  - d. Borrowed vaccine logs are to be completed and submitted (see Borrowed Vaccine Policy).
  - e. All VTckS pending shipments accepted.

By the 10<sup>th</sup> of the month, missing reports will result in the suspension of vaccine orders until the documents are received.

2. Vaccine Waste is categorized as avoidable or unavoidable.
  - a. **Unavoidable waste** occurs due to an act of nature that could not have been avoided (i.e., tornados, floods). Avoidable waste is under the control of the provider and is preventable.
  - b. **Avoidable waste includes, but is not limited to:**
    - i. Refrigerator/freezer left open;
    - ii. Temperatures out of range and no action taken, or data logger not downloaded when alarm indicates a problem;
    - iii. Vaccine left out overnight;
    - iv. Excessive vaccine ordering as compared to provider profile;
    - v. Failure to notify KIP 3 months in advance of vaccine expiration date when provider will be unable to use all the doses on hand. This will allow KIP to place the vaccine doses on the redistribution log. KIP will not list vaccines with expiration dates longer than 365 or less than 90 days. Listing vaccines on the redistribution log **does not** absolve the provider of responsibility. Providers who have excess vaccine should contact other VFC providers to determine if they could use the vaccine. Providers might share a box of vaccine with another provider versus ordering quantities they do not need and then wasting the doses;
    - vi. Failure to properly package vaccines when shipping to another provider resulting in waste (i.e., shipping without adequate cold/frozen packs);
    - vii. Vaccines with longer expiration dates administered prior to vaccines with shorter expiration dates;
    - viii. Patterns of client eligibility not determined prior to administering vaccination;
    - ix. Patterns of vaccine drawn but not used.

## Policy:

1. Providers with avoidable wasted vaccine will be expected to replace the wasted vaccine on a “dose for dose” basis. The provider shall replace the wasted vaccine within 90 days of the waste and shall submit a paid invoice showing the replacement of the wasted doses. As well as using the “replacement” category in WebIZ for the privately purchased vaccine to be used to VFC/CHIP children.
  - a. Providers will not be able to order the specific VFC/CHIP vaccine of which they are required to replace, until documentation has been provided the wasted doses have been replaced “dose for dose”
2. Providers are requested to specifically identify internal mechanisms to avoid future wastage and to submit these policies to KIP. Examples for avoidable wasted vaccine that will need a plan of action may be:
  - a. expired vaccines;
  - b. improper storage and handling;
  - c. equipment failures;
  - d. staff education on vaccine management practices (i.e., stock rotation);
  - e. ordering patterns (inventory on-hand versus monthly/quarterly use).

3. Providers with ongoing avoidable wasted vaccine may be placed on vaccine hold or may be dis-enrolled from the VFC program should the patterns of wastage continue.
4. Unavoidable wasted vaccines shall be monitored by KIP. Unavoidable waste includes vaccines lost due to natural disasters or equipment failure when the provider has followed their written vaccine emergency policies, including relocating the vaccines to safe storage in a timely manner. Providers who have insurance which covers these situations will be expected to replace all VFC wasted doses with the payment from the insurance company within 90 days of the incident. The provider will be asked to submit the paid invoice for the wasted vaccine. Federal law prohibits financial gain from VFC vaccines.
5. Any unusable vaccine occurring from waste, expiration, or other event must be reported and submitted on the VFC Wasted Vaccine in WebIZ within 72 hours of waste.
6. Providers who receive short-dated vaccines (less than 6 months to the expiration date from McKesson Distributors) are asked to report this to KIP immediately. Only in special circumstances are short-dated vaccines shipped. Good faith efforts to use short-dated vaccines will not be billed if wasted, unless the waste is due to gross negligence.
7. VFC providers who accept redistributed vaccine will not be billed for waste so long as the receiving provider has made a good faith effort to use all the vaccines prior to their expiration date.
8. All VFC providers will be monitored for patterns of waste.
9. Any VFC provider who has avoidable waste related to a temperature excursion will be required to have a Storage and Handling visit within 2 months.
10. Temperature Excursions-
  - a. Avoidable waste due to temperature excursions include-
    - I. Failure to comply with policy and notify by phone KIP when temperatures are out of range
    - II. Failure to monitor vaccine storage units with a certified calibrated thermometer (per Storage and Handling Policy)
    - III. Failure to take/ document corrective action to preserve viability of vaccine
    - IV. Multiple out of range temperatures.
    - V. Failure to complete temperature log completely
  - b. Unavoidable waste due to a temperature excursion
    - I. Out of range temperature causing vaccine loss, all policies followed including relocation of vaccine.
11. Unaccounted for or Lost vaccine-
  - a. Unaccounted for or lost vaccine is subject to 'dose for dose' replacement at anything greater than a total count of 3 vaccines per month.
    - I. If there is a (+) positive unaccounted vaccine, a child's chart is reflecting a vaccine that they did not receive; this will need to be corrected in their record.
    - II. If there is a (-) negative unaccounted vaccine, the vaccine is missing or lost and will need to be replaced dose for dose.
    - III. Any unaccounted for doses that exceed the 3 total vaccine limit will need to call KIP to close MIR and justify unaccounted doses.

#### **Return of vaccine**

1. Expired vaccine can be returned to McKesson.
2. Once vaccine has expired:
  - a. Remove wasted/expired/spoiled vaccine from storage units with viable vaccine to prevent inadvertent administration (this includes wasted/expired/spoiled diluents).
  - b. Label all expired/ spoiled vaccine: "DO NOT USE"
  - c. Report the expired vaccine within 72 hours in WebIZ

- d. Prepare and package the vaccine for return shipment pickup.
3. Vaccine that cannot be returned:
- a. Vaccine drawn into the syringe but not administered
  - b. Vaccine in open vial but doses not administered
  - c. Compromised vial
  - d. Lost or unaccounted for vaccine.

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